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APPLICATION NUMBER 09/172,990	FLING DATE 10/14/98	FIRST NAMED APPLICANT UZENBERGER	ATTY. DOCKET NO. B AHP-98126-
AMERICAN HOME PRODUCTS CORPORATION PATENT LAW DEPARTMENT 2B2 ONE CAMPUS DRIVE PARSIPPANY NJ 07054			EXAMINER GLICKER, S ART UNIT 1646 PAPER NUMBER 9
DATE MAILED: 04/12/00			

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 1/27/00
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.
- A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).
- Disposition of Claims**
- ☒ Claim(s) 1-24 is/are pending in the application.
- ☐ Of the above, claim(s) 6-10 + 12-24 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-5 + 11 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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*Response to Amendment*

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification as filed for polynucleotides encoding allelic variants or species homologues of BBP (clauses (a)-(h) of claim 1) wherein said polynucleotides encode an amino acid sequence that binds human  $\beta$ -amyloid peptide. This is a new matter rejection.
5. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention for reasons of record and the following. Claims 1-5 encompass the genus of polynucleotides encoding all species and allelic variants of  $\beta$ -amyloid peptide-binding protein (BBP). The specification does not adequately describe the genus of nucleotide sequences encoding all BBPs because a representative number of species have not been described by complete structure (University of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)). Only two nucleotide sequences are described by complete structure (human and rat). The specification teaches "the high degree of specificity of the BBP1/BAP interaction in the Y2H assays since the substitution of three amino acids was sufficient to completely abrogate the association (Figure 7)" (page 38, lines 25-28). Due to the high unpredictability in the molecular biology arts, the complete structure of any other encoding species of BPP is not adequately described such that one of skill in the art would conclude that Applicant had possession of what Applicant is claiming, i.e. a genus of encoding sequences for more than one species of BPP. Furthermore, a representative number of species have not been described by sufficient relevant identifying characteristics.

*Applicant's arguments filed 1/27/00 have been fully considered but they are not persuasive because Applicant argues that amending the claim such that the polynucleotides of (j) and (k) encode an amino acid sequence that binds  $\beta$ -amyloid peptide overcomes the rejection. However, amending the claim to recite a function of the encoded amino acid sequence does not overcome the grounds of rejection already applied because a representative number of species of*

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*nucleotides have not been described by sufficient relevant identifying characteristics in terms of their structure as set forth above.*

6. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and the following. The term homologue does not have clear metes and bounds in the art, and it cannot be applied quantitatively to establish clear metes and bounds. See Lewin, page 1570. In addition, "the polynucleotide" in claim 5, line 1, has no clear antecedent basis and is therefore vague and indefinite. Furthermore, clause (l) of claim 1 now recites limitations which refer back to clauses (j) and (k) of claim 1. It is vague and unclear whether Applicant intends for this new limitation to apply only to clauses (j) and (k) of claim 1, or if Applicant intends for this new limitation to apply to clause (l) of claim 1 as well as clauses (j) and (k) of claim 1. Appropriate correction is required.

*Applicant's arguments filed 1/27/00 have been fully considered but they are not persuasive because Applicant argues that the term homologue is defined by the specification on page 19, line 20 to page 20, line 9. No sufficiently limiting definition of homologue is found where Applicant asserts one is found. At best, reading down page 20, the specification describes preferable definitions of homologue, but no definition is given in the specification that would clearly and unambiguously define the metes and bounds of the instant claims. Preferable definitions of the term homologue do not define what other, non-preferable definitions of the term homologue are encompassed by the instant claims. "Significant sequence similarity" also*

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*does not place a clear and definite numerical value on what "homologue" means (page 20, lines 11-12) or what numerical value is deemed significant.*

7. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. ("Adams") for reasons of record and the following. Adams discloses sequence EST178050 which meets the limitations of clause 1 of claim 1 because "stringent conditions" (which would include very low stringency) would not exclude the sequence of Adams which shares 54.9% identity overall, and 98.1% best local identity, with instant SEQ ID NO:1. Because of the 98.1% best local identity, Adams meets the limitations of instant claim 11. Because the local identity is so high, the sequence of Adams would hybridize to the instant sequence or portion thereof and would inherently inhibit the expression of the BPP1 gene. It may be possible to obviate the grounds of this rejection by amending the claim to recite specific hybridization conditions that would exclude the sequence of Adams and by requiring that the antisense sequence is complementary to more than a portion of BBP1 sequence.

*Applicant's arguments filed 1/27/00 have been fully considered but they are not persuasive because Applicant asserts that "all sequence information [of Adams] does not appear to have been available as of that date." However, Applicant provides no evidence to support his assertion. Furthermore, Applicant's arguments drawn to any potential licensing agreements or waivers based on the prior art Adams reference does not remove this reference from the prior art. The teachings of Adams are publicly available and are therefore in the prior art regardless of whether to commercially or otherwise use those teachings other legal niceties must be*

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*observed. Clause (l) of claim 1 merely states hybridization; it does not recite a limitation of encoding a functional amino acid sequence of clause (l). Rather, it states this limitation in reference to clauses (j) and (k).*

8. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of Gellissen et al. ("Gellissen") for reasons of record and the following. The teachings of Adams are as set forth in ¶5 above. Adams does not teach expression or host cells. Gellissen teaches expression and host cells (abstract). It would have been obvious for one of ordinary skill in the art at the time the invention was made to express the polynucleotide of Adams using the expression system and host cells of Gellissen for the favourable characteristics taught by Gellissen (abstract).

*Applicant's arguments filed 1/27/00 have been fully considered but they are not persuasive because Applicant asserts that "all sequence information [of Adams] does not appear to have been available as of that date." However, Applicant provides no evidence to support his assertion. Furthermore, Applicant's arguments drawn to any potential licensing agreements or waivers based on the prior art Adams reference does not remove this reference from the prior art. The teachings of Adams are publicly available and are therefore in the prior art regardless of whether to commercially or otherwise use those teachings other legal niceties must be observed. Clause (l) of claim 1 merely states hybridization; it does not recite a limitation of encoding a functional amino acid sequence of clause (l). Rather, it states this limitation in reference to clauses (j) and (k). Since Adams has no deficiencies as asserted by Applicant, the*

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*rejection is maintained. In addition, Applicant asserts that there is no motivation to combine the references, but does not address the motivation to combine already of record.*

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0730 to 1600. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

April 10, 2000

*Gary L. Kunz*  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200